

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Cooperative Agreement to Support the Illinois Institute of Technology's  
National Center for Food Safety and Technology; Notice of Intent to Accept  
and Consider a Single Source Application; Availability of Funds for Fiscal  
Year 2004**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is announcing its intent to accept and consider a single source application for the award of a cooperative agreement to the Illinois Institute of Technology (IIT) to support the National Center for Food Safety and Technology (NCFST). FDA anticipates providing \$2,750,000 (direct and indirect costs) in fiscal year 2004 in support of this project. Subject to the availability of Federal funds and successful performance, 4 additional years of support up to \$5,000,000 per year (direct and indirect) will be available.

**DATES:** Submit applications by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Application forms are available from, and completed applications should be submitted to Maura Stephanos, Division of Contracts and Grants Management (HFA-531), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7183. If an application is hand-carried or commercially delivered, it should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857, FAX: 301-827-7101, e-mail: *mstepha1@oc.fda.gov*. Do

not send the application to the Center for Scientific Review, National Institutes of Health (NIH). An application not received by FDA in time for orderly processing will be returned to the applicant without consideration. FDA can not receive an application electronically.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the administrative and financial management aspects contact:*

Maura Stephanos (see **ADDRESSES**).

*Regarding the programmatic aspects contact:* Donald Zink, Center for Food

Safety and Applied Nutrition (HFS-300), Food and Drug

Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-

3835, 301-436-1693, FAX: 301-436-2632, e-mail: [dzink@cfstan.fda.gov](mailto:dzink@cfstan.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

FDA is announcing its intention to accept and consider a single source application from IIT (RFA-FDA-CFSAN-04-1) to support the NCFST. FDA's authority to enter into grants and cooperative agreements is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public. This application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100). The cooperative agreement is intended to maintain and facilitate the further development of NCFST for the purpose of enhancing food safety to the benefit of the public. Specifically, NCFST is expected to maintain its collaborative research program involving FDA, academia, and the food industry; to continue to focus its research and outreach

efforts on the safety of food processing and processed foods; to continue to maintain its food safety library resources; and to maintain and utilize its unique pilot plant resources to support the development and validation of new and emerging food processing technologies.

## **II. Background**

In the **Federal Register** of May 3, 1988 (53 FR 15736), FDA published a request for applications for a cooperative agreement to establish a National Center for Food Safety and Technology, which would join the resources of government, academia, and industry in a consortium to study questions of food safety. FDA awarded the cooperative agreement to IIT in September 1988. The applications received in response to this announcement were competitively reviewed by a panel of non-FDA food scientists, and the award to IIT was approved by the National Advisory Environmental Health Science Council in September 1988.

In the **Federal Register** notices of September 10, 1991 (56 FR 46189), May 12, 1994 (59 FR 24703), and July 22, 1999 (64 FR 39512), FDA published notice of its intention to limit consideration for the award of a cooperative agreement to IIT to support the NCFST. FDA awarded the cooperative agreement to IIT on September 30, 1991, September 26, 1994, and September 27, 1999, respectively, following competitive review of the applications by a panel of non-FDA food scientists. The award was approved by the National Advisory Environmental Health Sciences Council in September 1991, September 1994, and September 1999, respectively.

Under the cooperative agreement, NCFST was established by IIT to bring together the food safety and technology expertise of academia, industry, and FDA for the purpose of enhancing the safety of the food supply in the common

goal of enhancing and improving the safety of food for U.S. consumers. NCFST is structured so that representatives of participating organizations play a role in establishing policy and administrative procedures, as well as identifying long and short-term research needs. With this organizational structure, NCFST is able to build cooperative food safety programs on a foundation of knowledge about current industrial trends in food processing and packaging technologies, regulatory perspectives from public health organizations, and fundamental scientific expertise from academia. The structure and programs at NCFST positioned the center as a key component of FDA's food safety and security program. Specifically, the work at NCFST focuses on the development and evaluation of new food processing technologies and preventive technologies targeted to reduce or eliminate harmful chemical and microbial contamination of foods. Also, the center is the focal point for the agency's program on food packaging development and evaluation. The work at NCFST complements and feed into other activities at the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland. NCFST is still unique in that CFSAN's Division of Food Processing and Packaging is located at the center to facilitate the kind of close relationship between academia, government and industry that the project requires. Scientists from all three sectors can work together in the labs and pilot plant of the center on projects of common interest. Finally, IIT has cultivated a base of continuing support from the food industry in the form of industry members who contribute financial support to the center and provide management direction to the center to ensure that industry needs are addressed. There is not another existing center where FDA has access to the industry relationships and research resources present at NCFST.

### **III. Delineation of Substantive Involvement**

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

1. FDA will appoint a project officer or co-project officers who will actively monitor the FDA-supported program under this award.
2. FDA shall have prior approval on the appointment of all key administrative and scientific personnel proposed by the grantee.
3. FDA will be directly involved in the guidance and development of the program and of the personnel management structure for the program.
4. FDA scientists will participate, with the grantee, in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, co-authorship of publications.

### **IV. Availability of Funds**

It is anticipated that FDA will fund this cooperative agreement at a level approximately \$2,750,000 (direct and indirect costs) for the first year. An additional 4 years of support up to approximately \$5,000,000 (direct and indirect costs) each year will be available, depending upon fiscal year appropriations, and successful performance.

### **V. Reasons for Single Source Selection**

FDA believes that there is compelling evidence that IIT is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. IIT's Moffett Campus, where NCFST is located, is a unique research facility which includes an industrial-size pilot plant and smaller pilot plants for food

processing and packaging equipment, a pathogen containment pilot plant, a packaging laboratory, analytical laboratories, offices, containment facilities, classrooms, and support facilities which permit research from benchtop to industrial-scale. The industrial-size pilot plant is built to accommodate routine food processing and packaging research in a commercial atmosphere. The physical layout of the facility provides maximum versatility in the use and arrangement of equipment of both commercial and pilot size, and in the capability to simultaneously operate several different pieces of equipment without interference with each other. In addition to facilities to conduct routine processing research, there are facilities suitable for more complex research, notably a pathogen containment pilot plant research facility, funded by the State of Illinois, which has been used to study the survival of pathogens in aged cheeses. Other facilities include smaller containment facilities in which research involving use of components that may be potentially hazardous, such as pathogens in pasteurization or modified atmosphere packaging research, may be conducted.

Since 1988, IIT has provided an environment in which scientists from diverse backgrounds such as academia, government, and industry, have brought their unique perspectives to focus on contemporary issues of food safety. NCFST functions as a neutral ground where scientific exchange, about generic food safety issues, occurs freely and is channeled into the design of cooperative food safety programs. NCFST has become a center of cutting edge technologies, such as high pressure processing, pulsed electric field processing, electrical resistance processing, ultraviolet processing, and high pressure processing. Ongoing research on packaging materials is focused on providing more alternatives for use with irradiation. A workshop, with participation by

representatives of government, academia, and industry, was held to discuss the use of irradiation as an intervention to prevent microbial contamination of foods and the need to alternative packaging materials for use with this technology. This led to the development of cooperative research on the safety of polymeric packaging materials for in-package irradiation. This type of research fills existing gaps in knowledge and expertise associated with improving the safety of foods at a time when concern about food contamination and resultant illnesses is high. Most recently, NCFST has gained expertise in conducting research under biosafety level 3 conditions and is in the process of renovating a facility to accommodate this type of research.

This cooperative research will provide fundamental food safety information, in the public domain, for use by all segments of the food science community in product and process development, regulatory activities, academic programs, and consumer programs. A particular use of this type of data by both industry and public health agencies is in hazard analysis critical control point (HACCP) and other types of preventive control programs. Food manufacturers will use the information in the design of HACCP programs, for use in their plants, which prevent food safety hazards before they occur and enhance the safety of the final product. Public health agencies can design investigational techniques to meet the needs of HACCP systems used in manufacturing plants.

An academic degree program (which is not part of the cooperative agreement) in food safety science has been underway for several years at IIT. The program produces graduates with a foundation in food science and technology with specialization in food safety. Graduates from this program will manage quality control, safety assurance, and HACCP programs in industry.

They will design equipment and processes for use in the production and packaging of safe food products. In the public sector, regulatory and other public health organizations, these graduates will evaluate the adequacy of processing and packaging parameters to produce safe end products and they will manage regulatory and information programs enhancing the safety of the food supply and consumer knowledge about the food supply. Graduate students from IIT are gaining hands-on experience in food safety by participating in the cooperative food safety research program. Several masters of science degrees that included research conducted on cooperative projects have been granted by IIT, in disciplines such as engineering, since the inception of NCFST.

Collaboration between the public and the private sector is an efficient means for both to remain current with scientific and technical accomplishments from a food safety perspective. These collaborative programs will produce generic knowledge and expertise to be used by all segments of the food processing and packaging industry, as well as by public health organizations, regulatory agencies, and academic institutions in the performance of their roles in the food science community. The trend toward use of HACCP and other types of preventive programs in both the domestic and international food industry as a means of assuring safety of products and as a basis for harmonizing regulatory activities, is but one example of the need for and use of this food safety knowledge and expertise. Technology transfer mechanisms, which are developing out of the cooperative food safety programs, will facilitate the movement of advanced food processing and packaging technologies into the marketplace, while assuring the safety of those products.



## **VI. Submission Requirements**

The original and two copies of the completed grant application form PHS 398 (rev. 5/01) with copies of the appendices for each of the copies, should be submitted to Maura Stephanos (see **ADDRESSES**). The outside of the mailing package should be labeled “Response to RFA–FDA–CFSAN–04–1”. The application will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before (see **DATES** section). Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the Public Health Service (PHS) to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

## **VII. Reporting Requirements**

An annual financial status report (FSR) (SF–269) is required. The original and two copies of the report must be submitted to FDA’s Grants Management Officer within 90 days of the budget period expiration date of the agreement. Failure to file an annual FSR in a timely fashion may be grounds for suspension or termination of the agreement.

An annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report.

A final program progress report, FSR and invention statement must be submitted within 90 days after expiration of the project period of the cooperative agreement.

## **VIII. Review Procedures and Evaluation Criteria**

### *A. Review Procedures*

The application submitted by IIT will first be reviewed by grants management and program staff for responsiveness. The requested budget must not exceed \$2,750,000 (direct and indirect costs) for the first year. The application will be considered nonresponsive if it is not in compliance with this document. If the application is found to be nonresponsive, it will be returned to the applicant without further consideration.

The application submitted by IIT will undergo noncompetitive dual peer review. The application will be reviewed for scientific and technical merit by an ad hoc panel of experts based upon the applicable evaluation criteria. If the application is recommended for approval, it will then be presented to the National Advisory Environmental Health Sciences Council for their concurrence.

### *B. Review Criteria*

The application will be reviewed and evaluated according to the following criteria:

1. The application clearly demonstrates an understanding of the purpose and objectives of the cooperative agreement regarding a collaborative food safety and security program.

2. The application clearly describes the steps and a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the cooperative agreement. The application presents a clear plan and schedule of steps to accomplish the goals of the cooperative agreement.

3. The application establishes the applicant's ability to perform the responsibilities under the cooperative agreement including the availability of appropriate staff and sufficient funding.

4. The application specifies the manner in which interaction with FDA will be maintained throughout the life of the project.

5. The application specifies how IIT will monitor progress of the work under the cooperative agreement and how progress will be reported to FDA.

6. The application shall include a detailed budget that shows the following items: (1) Anticipated costs that are allowable and allocable to the project; and (2) the sources of funds to meet those needs.

#### **IX. Mechanism of Support**

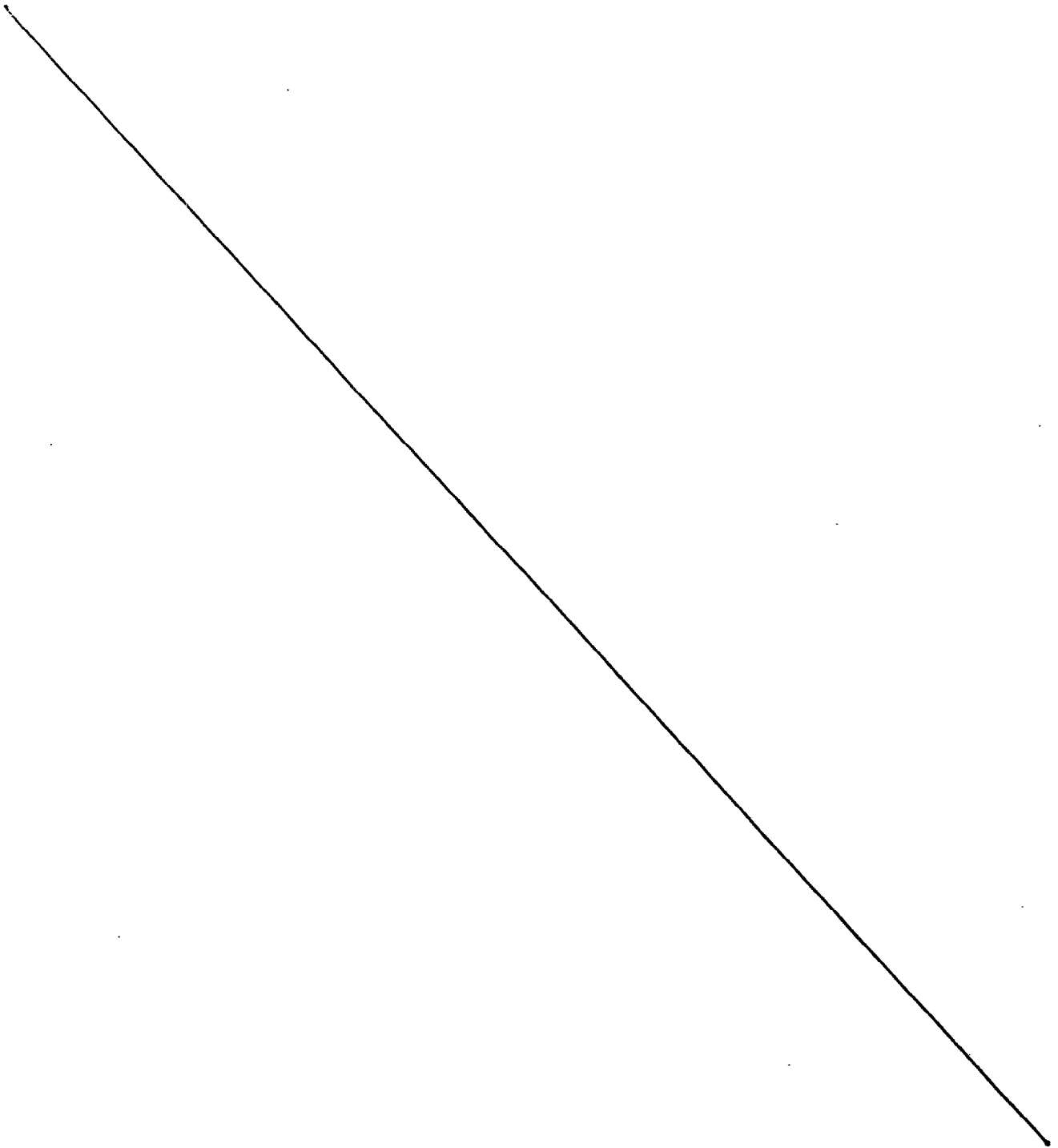
Support for this project will be in the form of a cooperative agreement. This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52, 45 CFR part 74, and PHS grants policy statement. The regulations issued under Executive Order 12372 do not apply. The length of support will be 1 year. Cost sharing or matching is not a requirement of this program. The NIH modular grant program does not apply to this FDA program.

#### **X. Dun and Bradstreet Number Requirement**

Beginning October 1, 2003, applicants will be required to have a Dun and Bradstreet Number (DUNS) to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

**XI. Legend**

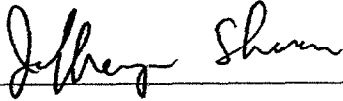
Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page



number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: APR 29 2004

April 29, 2004.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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